Exhibit C

True Excerpts from the Amicus Brief filed by the Aimed Alliance in support of Amarin's Petition for Certiorari to the United States Supreme Court, dated March 4, 2021

No. 20-1119

In the
Supreme Court of the United States

AMARIN PHARMA, INC. and
AMARIN PHARMACEUTICALS IRELAND LIMITED,
Petitioners,

v.

HIKMA PHARMACEUTICALS USA INC.,
HIKMA PHARMACEUTICALS INTERNATIONAL LIMITED,
DR. REDDY'S LABORATORIES, INC. and
DR. REDDY'S LABORATORIES, LTD.,
Respondents.

On Petition for Writ of Certiorari to the
United States Court of Appeals for the
Federal Circuit

BRIEF FOR *AMICUS CURIAE* AIMED ALLIANCE IN SUPPORT OF PETITIONERS

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the drug provides such a "substantial benefit with respect to major adverse cardiovascular events." John J.P. Kastelein & Erick S.G. Stroes, *FISHing for the Miracle of Eicosapentaenoic Acid*, 380 N. Engl. J. Med. 89, 89, 90 (2019). In fact, *The New England Journal of Medicine* deemed the study's results to be so significant that its editorial board selected a story on Vascepa®'s clinical results as its top story concerning "the most important research in the field from the past year." Harlan M. Krumholz, NEJM Journal Watch Cardiology *2018 Top Stories* (Dec. 26, 2018). Similarly, the American Heart Association included Vascepa®'s clinical results in its "annual list of major [research] advances in heart disease and stroke." Am. Heart Ass'n, *AHA Names Top Heart Disease and Stroke Research Advances of 2018*, Heart.org (Dec. 31, 2018).

Both the Federal Circuit and the district court brushed aside these important objective indicia that Amarin's invention was not obvious. Their failure to consider the totality of evidence was driven not only by improper 20/20 hindsight, but also more fundamentally by their failure to apply the correct legal standard. The Federal Circuit's burden-shifting approach was dispositive of the outcome of this case.

II. The Question Presented Is Very Important.

The patent system that Congress created seeks to achieve a careful balance between incentivizing pathbreaking inventions and enabling robust competition. In the drug context, this balance is vital to encouraging manufacturers to develop innovative treatments that respond to unmet needs, and to ensuring that innovative treatments are affordable

and accessible to patients. The Hatch-Waxman Act balances these considerations by creating a simplified procedure "to speed the introduction of low-cost generic drugs to market," *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012), while simultaneously extending patent protection to incentivize companies "to develop and market products." *Pfizer Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004). Both components—patent protection and simplified generic approval—are important to the patient community and for improving public health.

Many Americans cannot afford medical services or treatments due to high out-of-pocket costs, causing them to choose between forgoing vital care and taking on significant debt or even bankruptcy. *See* Michael Sainato, *The Americans Dying Because They Can't Afford Medical Care*, Guardian (Jan. 7, 2020). For that reason and others, FDA has taken significant steps to accelerate the approval of generic drugs. The benefits of generic competition, however, cannot be realized unless a novel drug is developed in the first instance and the public knows about it. That is why competitors must wait until patent exclusivity expires before they can sell a generic version of an FDA-approved drug. *See* 35 U.S.C. § 271(e)(3), (4)(A)–(B).

Patent protection is important because it incentivizes pioneering companies to undertake costly research and development to discover new treatments and bring them to market. Bringing a new drug to market requires a massive investment. Indeed, recent estimates suggest that the average research-and-development costs of bringing a new drug to market

are nearly $2.6 billion. *See* Joseph A. DiMasi, Henry G. Grabowski, & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 31 (2016).

Bringing a new drug to market also entails significant risk, not least because relatively few new drugs are successful. Government studies suggest that only 20 in 5,000 compounds (approximately 0.4%) of screened compounds ever enter preclinical testing in laboratories and on animals. *See* FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3, at 6 (2003). Moreover, "95% of drugs that enter clinical trials do not make it to the market." Thomas Hartung, *Food for Thought Look Back in Anger – What Clinical Studies Tell Us About Preclinical Work*, 30 ALTEX 275, 275 (2013). In addition, when a compound is found to be adequately safe to test on humans, there are three phases of clinical testing, each of which is required to determine the compound's safety and efficacy. *See* FTC, To Promote Innovation, *supra*, ch. 3, at 6. As a result, developing and commercializing a drug often takes more than a decade. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 475 (2007).

Without patent protection, most companies would not undertake the investments necessary to develop an innovative drug for patients, only to face immediate competition from generic versions. Here, for example, Amarin spent "$465 million in research and development" to discover Vascepa®'s second indication to reduce the risk of cardiovascular events

for patients. App. 55a. That second indication represented the culmination of years of clinical development that succeeded where others had failed. *See* Deepak L. Bhatt et al., *Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia*, 380 N. Eng. J. Med. 11, 12 (2019); Press Release, Amarin Corp., Amarin Receives FDA Approval of Vascepa® (Icosapent Ethyl) to Reduce Cardiovascular Risk (Dec. 13, 2019). Even with patent protection, it is reported that Amarin investors do not expect to recoup their investment in Vascepa® until 2024. *See* App. 55a.

Beyond fostering innovation, patent protection also encourages patent holders to educate patients, caregivers, and health-care providers about new treatments. The district court noted that "marketing spending tends to be higher at the beginning of a pharmaceutical product's lifecycle, given the need to educate physicians about the clinical profile of the new drug in question." App. 55a. While that is true, it is also true that when a company conducts additional groundbreaking research, or when a medication receives expanded approval for new indications, renewed efforts are needed to educate patients, caregivers, and health-care providers.

The hard reality is that without patent rights, many patients will remain in the dark. Significantly, although Amarin received initial approval for Vascepa® in 2012, it did not receive its second indication until December 2019 (just months before the district court's judgment). *See* App. 3a, 25a. As a result, health-care providers, caregivers, and patients are only beginning to understand and appreciate the

significance of the new indication. But because Vascepa® is Amarin's only product, the company is unlikely to maintain its nascent educational campaign if its efforts are undercut by generic competition. And generic competitors are unlikely to make up the difference because that is not part of their business model. *See* Curt D. Furberg, Bengt D. Furberg, & Larry D. Sasich, Knowing Your Medications: A Guide to Becoming an Informed Patient 56 (2009) (noting that "generic manufacturers spend much less on marketing and accept much lower profit margins" than brand-name manufacturers").

There is thus an important public need to maintain the incentives for Amarin to educate healthcare providers on the benefits of its pathbreaking drug. Cardiovascular disease has long been the leading cause of mortality in the United States. *See* CDC, *Heart Disease Facts*, CDC.gov (Sept. 8, 2020). Although the number of deaths due to heart disease declined substantially between 2000 and 2010, the trend has since reversed. *See* Sally C. Curtin, *Trends in Cancer and Heart Disease Death Rates Among Adults Aged 45-65: United States 1999-2017*, 68 Nat'l Vital Stat. Rep. 1, 2, Fig. 1 (May 22, 2019); *see also* CDC, *Data Brief No. 254: Changes in the Leading Cause of Death: Recent Patterns in Heart Disease and Cancer Mortality* 1, 1 (Aug. 2016). Nearly 650,000 Americans die from heart disease each year—"that's *1 in every 4 deaths*." CDC, *Heart Disease Facts*, *supra*. About 805,000 Americans suffer a heart attack each year. *Id.* More than 30 million Americans take statins. *See* Peter Wehrwein, *Statin Use Is Up, Cholesterol Levels Are Down: Are Americans' Hearts Benefiting?*, Harv. Health Pub. (Apr. 15, 2011).

Between 50 to 70 million adults in the United States have high levels of triglycerides. Campbell, *Is It Time to Ditch Your Fish Oil Pills*, *supra*. These statistics coincide with the CDC last year listing "heart conditions" as presenting an "increased risk of severe illness from the virus that causes COVID-19." CDC, *COVID-19, People with Certain Medical Conditions*, CDC.gov (Dec. 29, 2020).

Information presented by Amarin's scientists to the American College of Cardiology suggests that Vascepa® may help prevent more than 70,000 cardiovascular events each year in adults in the United States with known cardiovascular disease or diabetes. *See* Press Release, Amarin Corp., Amarin Highlights VASCEPA® (Icosapent Ethyl)-Related Data Presented at American College of Cardiology's Annual Scientific Session Together with World Congress of Cardiology (ACC.20/WCC) (Mar. 31, 2020). Moreover, because Vascepa® is "highly cost-effective," it could be the "rare[]" therapy that results in "net healthcare cost-savings to patients, payers and society." *Id.*

There is thus "no doubt that" Amarin's Vascepa® "is a medication that could benefit a substantial portion of the U.S. and meets an unmet need." Trisha Roy & Saumya Joseph, *FDA Panel Unanimously Backs Expanding Use of Amarin's Heart Drug Vascepa®*, Reuters (Nov. 14, 2019) (quoting Dr. Jack Yanovski of the National Institutes of Health). It represents a significant step forward—an innovative advance in the treatment of cardiovascular disease and severe hypertriglyceridemia—that is now available to meet a previously unmet need for

patients, provided that Amarin continues to invest in publicizing its life-saving drug so that patients, caregivers, and health-care practitioners are adequately aware of the medication's benefits. In short, Vascepa® is precisely the type of invention that patent law is designed to encourage and protect. The Federal Circuit's decision to the contrary is worthy of this Court's review.

* * *

The Federal Circuit has made up a test for which there is no support and on which actual public-health outcomes turn. If the Federal Circuit's precedential departures are not corrected, they will undermine the patent system by discouraging pioneering companies from pursuing the development of innovative treatments for serious diseases. As a result, new medications that treat otherwise unmet medical needs may not be available to the patients who need them. More immediately, without patent protections, Amarin will be unable to continue making the investments needed to educate patients, caregivers, and health-care providers about Vascepa®'s clinical trial results and its newly discovered benefits. In addition, many health-care practitioners may never become aware of, and therefore may not prescribe, a treatment to patients for whom Vascepa® may be medically necessary.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted.

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